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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,910	11/28/2000	Hugh J. Pasika	7414.0025	8658

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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/724,910

Applicant(s)

PASIKA ET AL.

Examiner

Channing S. Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 4, 5, 7-13, 16-24, 26, 27, and 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 6, 14, 15, 25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *APPLICANTS' ARGUMENTS*

Applicants' arguments in Paper No. 14, filed 20 February 2003, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 3, 6, 14, 15, 25, and 28. Claims 1, 2, 4, 5, 7-13, 16-24, 26, 27, and 29-33 remain withdrawn.

### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

#### *SCOPE OF ENABLEMENT*

For reasons of record the rejection of claims 3, 6, 14, 15, 25, and 28 under 35 U.S.C. § 112 1<sup>st</sup> Paragraph as indicated in Paper No. 12, mailed 05 November 2002, is maintained.

Applicants have failed to address scope of enablement issues as indicated in Paper No. 12, mailed 05 November 2002, pages 3-4 of the office action. Applicants state in Paper No. 14, filed 20 February 2002:

“Although the Examiner lists factors, summarized in In re Wands, to be considered in determining whether a disclosure would require undue experimentation, the Examiner has not addressed a particular factor. Thus, Applicants need not address those factors.”

The rejection regarding scope of enablement in Paper No. 12, mailed 05 November 2002, pages 3-4, is reiterated wherein undue experimentation was addressed; particularly the factor regarding the amount or direction presented (i.e. lack of guidance; underlined):

"The below explanation not only provides for the lack of enablement rejection, but additionally a scope of enablement rejection regarding the step of "making an allele call", which is not commensurate in scope with the specification. The Envelope Caller assesses the complexity of the signal from the nucleic acid sequencer prior to "making an allele call". If the signal's complexity is below a threshold the Envelope Caller makes the call (page 13, lines 5-7 of the Specification) and this call "stands an excellent chance of being correct" (page 13, lines 8-9 of the Specification), though this does not indicate that the call is indeed "correct". Whether or not the Envelope Caller should "make an allele call" requires that the algorithm first to determine if three panels exist (page 14, lines 7-8 of the Specification), wherein the original signal is divided into panels at each minimum (page 14, lines 4-5). The energy level for each panel (complexity) is computed by summing the square of each element in the panel. The energy levels of the three panels must be of sufficiently low complexity for the Envelope Caller to operate/call; as defined threshold for the complexity is when: E2 is greater than 20% of E1 and E3 is no more than 7% of E2 (page 15, lines 1-5 of the Specification). It should be noted that the specification recites "If, at least three panels exist ...", unclear is the threshold determination if more than three panels exist. Additionally, none of the above steps or elements are limitations of the claims, and the specification does not provide guidance as to other types of analysis or ways to perform these steps.

Further, claims 3 (line 4), 14 (line 5), and 25 (line 5) are not commensurate in scope with the specification with regard to the instantly claimed step of "determining a complexity of a signal". As stated above, the energy level for each panel (complexity) is computed by summing the square of each element in the panel. No other methods of "determining a complexity of a signal" are disclosed and the specification provides no guidance as to other methods for "determining a complexity of a signal" that could be used (page 14, lines 10-11)."

Therefore, the arguments are non-persuasive to overcome the rejection.

**Claims Rejected Under 35 U.S.C. § 102**

For reasons of record the rejection of claims 3, 6, 14, 15, 25, and 28 under 35 U.S.C. § 102(b) as being anticipated by Perlin (U.S. Patent No. 5,580,728) as indicated in Paper No. 12, mailed 05 November 2002, are maintained. Further, clarification of the rejection is provided below with regard to applicants' argument(s).

Applicants argue in Paper No. 14, filed 20 February 2003, that Perlin fails to teach "each and every element" of the claims. Particularly, Perlin "fails to teach using a complexity relating to at least energy levels associated with the signal to make an allele call".

As indicated in Paper No. 9, mailed 15 May 2002, Perlin teaches a method and system for determining the alleles of STR genetic markers wherein gel images are electronically scanned and the collected data signals are recorded as a linear fluorescence signal trace (i.e. energy level), which automatically creates machine-readable data files via software (Abstract; Column 11, lines 27-39; and Column 12, lines 8-11). Further, the office action indicated that the said signal peaks are identified and assigned a time and an area, such that the apex of the peak exceeds a predetermined threshold/complexity (Column 12, lines 47-54). Thus, the "complexity relating to at least energy levels associated with the signal" is used to make an allele call. Therefore, the arguments are non-persuasive to overcome the rejection.

For reasons of record the rejection of claims 3, 6, 14, 15, 25, and 28 under 35 U.S.C. § 102 (e) as being anticipated by Hiller et al. (U.S. Patent No. 6,274,317 B1) as indicated in Paper No. 12, mailed 05 November 2002, are maintained. Further, clarification of the rejection is provided below with regard to applicants' argument(s).

Applicants argue in Paper No. 14, filed 20 February 2003, that Hiller et al. fails to teach "each and every element" of the claims. Particularly, Hiller et al. "does not use a complexity relating to at least energy levels associated with the signal to make an allele call".

As indicated in Paper No. 9, mailed 15 May 2002, Hiller et al. teaches a computer system for allele calling based on matching by identifying alleles from trace data (i.e. energy level) wherein a DNA sequencer scans the gel to produce an image in digital format (Abstract; Column 2, lines 32-41; Column 2, lines 47-48; Column 3, lines 58-60). Adjacent peaks can be filtered to within a predetermined number of base pair distance/threshold/complexity (Column 9, lines 24-64). Thus, the "complexity relating to at least energy levels associated with the signal" is used to make an allele call. Therefore, the arguments are non-persuasive to overcome the rejection.

*ACTION IS FINAL*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**No Claims Are Allowed.**

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*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

*May 16, 2003*

Examiner Initials:

*CSM*

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1800  
*Art 1631*